REMARKS

Claims 1-24 are pending in the present application. Claims 3-11 and 16-24 were withdrawn from consideration. By virtue of this response, claims 1-2 and 13 have been amended and new claims 25 and 26 have been added. Accordingly, claims 1-2, 12-15, 25, and 26 are currently under consideration. Support for amended claims 1 and 13 is provided throughout the specification, such as on page 13, paragraph [0040], and on page 30, paragraph [0087]. Support for new claim 25 is provided throughout the specification, such as on page 3, paragraph [0010]. Support for new claim 26 is provided throughout the specification, such as on pages 39-40, paragraph [0111] . No new matter has been added.

With respect to all claim amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in a future continuation and/or divisional application.

Claim Rejections – 35 U.S.C. § 112, First Paragraph, Deposit Requirement

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner states that a deposit of the hybridoma Accession Nos: PTA-4217, PTA-4218, PTA-4244, and PTA-4245 would satisfy the requirements of 35 U.S.C. §112, first paragraph, and Applicant is required to submit a statement reciting that all restrictions upon public access to the deposits will be irrevocably removed upon the granting of a patent on this application, and that the deposit will be replaced if viable sample cannot be dispensed by the depository.

In response, Applicants respectfully submit a copy of the deposit receipts for the host cell lines and a declaration by Penelope E. Roberts, an inventor of the present application, assuring the availability of the deposit as required under 37 C.F.R. §§1.801-1.809.

In view of the above, Applicants respectfully submit that claim 15 and new claims 16 are enabled and request that the rejection be withdrawn.

Sequence Rule

The Examiner alleges that the application fails to comply with the requirements of 37 C.F.R. 1.821-25 because the specification recites sequences without being accompanied by sequence identification numbers, for example, the sequences on tables 1-2 on page 66.

Applicants respectfully note that a preliminary amendment was filed on August 3, 2006 to amend the specification to include sequence identifiers. Applicants further note that it is not required to include sequence identifiers in Table 1 under the sequence rule. Applicants respectfully request that this objection be withdrawn.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 1-2, 12-15 are rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that claims 1-2, 12-14 are indefinite for the use of language "RAAG10" in claims 1, 13, as the sole means of identifying the claimed antigen. The use of laboratory designation only to identify a particularly antigen renders the claim indefinite because different laboratories may use the same laboratory designations to define completely distinct antigens. Amendment of the claims to incorporate for example, a sequence identification number, to include physical and/or functional characteristics of "RAAG10" which unambiguously define "RAAG10", is suggested.

Applicants respectfully traverse. However, in the interest of expediting the prosecution and without acquiescing to the merits of the Examiner's rejection, claims 1 and 13 have been

amended to recite the antigen "B7H3L". Applicants respectfully request that this rejection be withdrawn.

The Examiner states that claim 15 is indefinite, because it is not clear what constitute "a progeny" of a cell line.

Applicants respectfully traverse. Applicants respectfully submit that the term "progeny" as used in claim 15 is clear and defined in the specification. Paragraph [0054] on page 18 of the specification provides that a progeny of a host cell includes any cell that originates from a parent cell. Accordingly, Applicants respectfully request that the rejection be withdrawn.

In view of the above, Applicants respectfully submit that claims 1-2 and 12-15 are definite and respectfully request that the rejections under 35 U.S.C. §112, second paragraph be withdrawn.

Claim Rejections – 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-2, 12-14 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse. Applicants respectfully that the claimed invention is well-described and based on the specification, one of ordinary skill in the art can recognize that Applicants had possession of the claimed invention at the time of filing.

The specification provides both molecular and biochemical characterization of the antigen target and antibodies of the claimed invention. The specification defines RAAG10 to refer to B7H3L, a polypeptide antigen with a glycosylated molecular weight of approximately 100kD (See page 13, paragraph [0040]). Additionally, the pending specification provides working

examples that identify the antigen target of the claimed invention. Example 6 of the pending specification discloses mass spectrometry analysis of the antigen bound by the antibodies the instant invention. Although the sequences of the peptides generated from mass spectrometry matched that of B7 homolog 3, or 2Ig-B7H3 (NCBI Accession number 13376852), the deglycosylated molecular weight of the purified antigen was approximately twice of the predicted molecular weight for 2Ig-B7H3 (See page 57, paragraphs [0163]-[0164] of the instant specification). Using the molecular weight data combined with comparisons with a human EST sequence (602309922F1 NIH_MGC_88 Homo sapiens cDNA clone IMAGE: 4401173 5'), Applicants concluded that the antibodies of the instant invention bind to a larger variant of B7H3 that contained 4Ig-like domains, a transmembrane domain and a cytoplasmic tail (see pages 58-59, paragraph [0165]). Applicant termed this larger variant of B7H3 (4Ig) to be B7H3L. In further experiments to characterize B7H3L, Applicants also provided a working example of cDNA cloning of B7H3L from a human ovarian cancer cell, SKOV3, cDNA library (see Example 10 of the instant specification).

In addition to the identification of the antigen target of the claimed invention as B7H3L, the pending specification also discloses at least seven different monoclonal antibodies against this target antigen generated using the methods taught in the specification and the different epitopes to which the family of antibodies bind (see page 62, paragraph [0175] of the specification). These monoclonal antibodies fell into three groups: Epitope A, to which PA20 binds; Epitope B, to which LUCA1 binds; and Epitope C, to which BLA8 binds (see pages 61-62, paragraph [0175] of the specification). Figure 2 and Table 3 of the specification further describe these three epitopes using deletion mutants.

In light of the above, Applicants respectfully submit that the written description requirement is met and request the withdrawal of this rejection.

Claim Rejections – 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-2, 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants respectfully traverse and submit that the specification clearly teaches how to make and use the invention as claimed.

As explained above, the specification clearly teaches that the antigen target of the claimed invention, RAAG10, is B7H3L. Furthermore, the specification teaches how to generate monoclonal antibodies against this antigen target and disclose several working examples of monoclonal antibodies against this antigen target. One of ordinary skill in the art, following the methods taught by the pending application, can, without undue experimentation, make the invention as claimed.

The Examiner further states that one cannot predict that the claimed antibody could be successfully used for treating cancer, in view that cancer treatment is highly unpredictable. Applicants respectfully disagree with the Examiner. The specification teaches how to generate and characterize monoclonal antibodies against the antigen target of the claimed invention and how to use these antibodies in the diagnosis of cancer and in the treatment of diseases, including cancer. The specification also includes working examples of a number of antibodies generated against the antigen target of the claimed invention. These antibodies were used to screen tumor tissues of various origins, including lung cancer, colon cancer, prostate cancer and breast cancer (see Example 11 of the pending specification). The specification also teaches how to use antibodies of the claimed invention for therapeutic purposes (see Section VIII, pages 39 to 48). Example 14 is a working example of in vitro cancer cell growth reduction using antibodies of the claimed invention with a toxin conjugate.

In light of the foregoing remarks, Applicants respectfully submit that one of ordinary skill in the art, following the teachings of the pending application, would be able to make and use antibodies of the claimed invention in methods of treating cancer, and request the withdrawal of this rejection under 35 USC § 112, first paragraph.

The Examiner has rejected claim 15 under 35 USC §112, first paragraph stating that one cannot predict that the monoclonal antibody produced by PTA-4244 cell line (PA20) could be used for diagnosing or treating lung cancer, because the monoclonal antibody produced by PTA-4244 cell line could not detect a difference in the level of the targeted RAAG10 between lung cancer tissue and normal lung tissue. Applicants respectfully disagree and submit that the antibody produced by PTA-4244 cell line can distinguish between lung cancer tissue and normal lung tissue.

As disclosed in Tables 7-8, on pages 72-73, PA20 (antibody produced by cell line PTA-4244), binds to two out of 6 lung cancer samples (or 33%), whereas, there was no appreciable binding to normal lung epithelium or alveoli. In another survey, RAAG10 or B7H3L was present on 6/6 lung tumor samples (see Table 4 of the pending specification). Diagnostic assays used in research and clinical settings typically detect differences in binding incidence far less than 33%. The applicants submit that the differential binding of tumor and normal tissue presented by the antibody produced by PTA-4244 cell line is sufficiently sensitive and significant for uses related to its use for the diagnosis and treatment of cancers that bind this antibody.

In light of the foregoing remarks, the applicants respectfully submit that following methods taught in the pending specification, one of ordinary skill in the art would be able to use the claimed cell line PTA-4244 for diagnosing or treating lung cancer and request the withdrawal of this rejection under 35 USC § 112, first paragraph.

The Examiner has also rejected claim 15 under 35 USC § 112, first paragraph, stating that one would not know how to make a progeny of the claimed cell line such that it would produce an antibody that could be used for diagnosis of a lung cancer. Applicants respectfully disagree with the Examiner. Methods of culturing and propagating hybridoma cell lines are well-known in the art and are routinely practiced by one of ordinary skill in the art. Combined with specific methods taught in the pending application, one of ordinary skill in the art would be able to culture and propagate the claimed cell line. In light of the foregoing amendment and remarks, the applicants respectfully request the withdrawal of this rejection under 35 USC § 112, first paragraph.

Claim Rejections – 35 U.S.C. § 102

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,891,030 (Chen, filed on 07/26/01), as evidenced by Banki et al, 1994, JBC, 269 (4): 2847-51, or Bendayan et al, 1995, J Histochem Cytochem, 43(9): 881-886).

Applicants respectfully traverse and submit that none of the above cited references teach the claimed invention, alone or in any combination.

Claims 1 and 2 as amended recite that the antibody specifically binds to a conformational epitope on B7H3L (RAAG10), which is not the "B7H3" disclosed in Chen et al. Chen et al. discloses the DNA sequence for B7H3 that contains 2Ig-like domains. B7H3L refers to a B7H3 that contains 4Ig-like domains. None of the references discloses a B7H3 that contains 4 Ig-like domains (B7H3L), or discloses an antibody that specifically binds to a conformational epitope on B7H3L as claimed.

In light of the foregoing remarks, Applicants respectfully submit that none of the cited references, alone or in any combination, anticipate the claimed invention and request the withdrawal of this rejection under 35 U.S.C. § 102(e).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 415072002500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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